Remarks:

A. Status of the Specification

The title of the specification has been amended at the request of the Action. Support for the title can be found throughout the specification and claims as originally filed. The objection to the title of the specification should therefore be withdrawn.

B. Status of the Claims

Claims 33-47 were pending at the time the present Office Action was issued from the U.S. Patent and Trademark Office. Claims 33-36, 38, and 40-47 have been amended, claim 37 has been cancelled, and claims 48-58 have been added. Support for the amendments and new claims can be found throughout the specification and claims as originally filed. Claims 33-36 and 38-58 therefore are currently pending.

C. The Objection of Claims 42 and 44-46 Should Be Withdrawn

The Action rejects claim 42 because the claim depends upon itself. Claims 44-46 are rejected under 37 C.F.R. § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants have amended these claims at the suggestion of the Action. The objection of claims 42 and 44-46 should therefore be withdrawn.

D. The Indefiniteness Rejections Are Improper

The Action rejects claims 33-47 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Nine separate indefiniteness rejections have been made.

Applicants traverse these rejections. The present claims are definite and satisfy all of the requirements under 35 U.S.C. § 112, second paragraph. Applicants address each rejection separately in the following sub-sections.

1. Claims 33-47 Are Definite

The Action contends that claims 33-47 are indefinite because the phrase "said sample" appears in claims 33 and 44-46. At the suggestion of the Action, these claims now recite "said biological sample." The present rejection should therefore be withdrawn.

2. Claims 34-35 Are Definite

The Action takes the position that claims 34-35 are indefinite because the phrase "suitable for digestion together with said biological sample" is subject to multiple interpretations. The Action states that "it does not appear that the sheets of material are digested with the biological sample." The Action page 4.

Applicants traverse. The phrase "suitable for at least partial digestion together with said biological sample" is definite and satisfies all of the requirements of 35 U.S.C. § 112, second paragraph.

A person skilled in the art would understand the phrase "suitable for digestion with said biological sample" when read in light of the specification. *See* MPEP § 2173.02 ("The test for definiteness under 35 U.S.C. § 112, second paragraph is whether those skilled in the art would understand what is claimed when read in light of the specification.") (citations and internal quotations omitted); *see also Miles Lab., Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993) ("If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, [section] 112 demands no more"). The specification, for example, explains that:

> ***The sample together with the part of said storage means is digested by conventional means for analysis.*** In the case of DNA for PCR analysis, this may be by a conventional alkali extraction or phenol/chloroform extraction. In this step, the material making up said storage means may dissolve or partially dissolve, but at least should not interfere with development of the DNA profile.

The specification, page 7, lines 19-26 (emphasis added).

> It will be appreciated that the punch removes the biological sample together with those portions of both the base sheet 11 and cover sheet 13 which encase it. The biological sample 18 does not need to be removed from the sample storage device 10 prior to analysis, hence the possibility of cross-contamination is minimized and the opportunity for tampering with the sample or substitution with another sample is limited even at the analysis stage. ***The sub-sample 26 [which includes the biological sample, the base sheet, and the cover sheet] that is punched out will immediately be placed in an appropriate vessel for digestion and subsequent analysis in the conventional manner.***

Id. at page 13, lines 16-27 (emphasis added).

It is clear from at least the passages cited above that the biological sample and at least a portion of the storage device are configured to be digested together. This is confirmed by at least Example 1 of the specification—a non-limiting embodiment of the present invention. *Id.* at page 14, line 25, to page 15, line 17. Example 1 shows a sub-sample—which includes a biological sample and at least a portion of a storage device—being digested together for subsequent analysis. *Id.* Contrary to the Action's position, the sub-sample is at least partially digested by the addition of a 200mM sodium hydroxide solution and a solution comprising 200mM HCl and 100mM Tris HCl. If this were not the case, subsequent analysis of the biological sample in Example 1 could not occur.

The specification is clear in that at least a portion of the storage device is digested with the biological sample. The phrase "suitable for at least partial digestion together with said biological sample" is therefore definite when read in light of the specification. The rejection of claims 34-35 under 35 U.S.C. § 112, second paragraph, should therefore be withdrawn.

3. Claim 35 Is Definite

Claim 35 is rejected for indefiniteness over the use of the phrase "substantially irreversibly adhered together." The Action contends that this phrase is "relative" which renders the claim indefinite. It appears that the Action is concerned with the term "substantially."

Applicants traverse. The phrase "substantially irreversibly adhered together" is definite and satisfies all of the requirements of 35 U.S.C. § 112, second paragraph. A person of skill in the art would understand the scope of this claim when read in light of the specification. The term "substantially," in fact, is an acceptable claiming term and does not render claim 35 indefinite. *See* MPEP § 2173.05(b)(D) (listing cases holding that the use of the term "substantially" in a claim does not make that claim indefinite). Claim 35, however, no longer recites the term "substantially." This rejection should therefore be withdrawn.

4. Claims 36-41 Are Definite

The Action separately rejects claims 36-41 for lack of antecedent basis. The claims have been amended to correct any antecedent basis issues. Applicants request that the indefiniteness rejections be withdrawn.

E. The Anticipation Rejections Are Improper

1. Claims 33-47 Are Not Anticipated by U.S. Patent No. 5,858,770 to Perlman

Claims 33-47 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,858,770 to Perlman. The Action contends that Perlman teaches a cell culture plate with an oxygen and carbon-dioxide permeable waterproof sealing membrane. The Action further contends that the cell culture plate is covered and sealed with the membrane and that the membrane can be made from polyester, polypropylene, or polyethylene.

Applicants traverse this rejection. Perlman does not anticipate claims 33-47, either expressly or inherently.

Anticipation requires that each and every element of the claimed invention be described, either expressly or inherently, in a single prior art reference. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327, 58 U.S.P.Q.2d 1545, 1552 (Fed. Cir. 2001); *Verdegaal*

Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). It is well settled that the burden of establishing a *prima facie* case of anticipation resides with the Office and only if that burden is met, does the burden of going forward shift to the applicant. *See In re Sun*, 31 U.S.P.Q.2d 1451 (Fed. Cir. 1993).

Applicants presently claim "[a] device for collecting and storing a biological sample for subsequent analysis, comprising a tamper-evident storage structure configured for storing said biological sample, ***said storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis***." Claim 33 (emphasis added). In another aspect of the present invention, the storage structure comprises a base sheet arranged so that the biological sample may be positioned thereon; a cover sheet configured to be secured to said base sheet, wherein said cover sheet comprises a polymeric film; and a backing sheet releasably secured to the surface of said cover sheet facing said base sheet. Claim 55.

Perlman does not appear to teach or suggest a storage device comprising a "storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis."[1] Rather, this reference appears to be directed towards a cover for a cell culture plate that can be used for culturing and manipulating living cells. *See* Perlman, col. 1, lines 6-11. The cell culture plates can be sealed with an oxygen and carbon dioxide-permeable waterproof sealing membrane. *Id.* The membrane allows living cells "to grow and survive within a sealed leak-proof culture plate." *Id.* at col. 2, lines 5-6.

[1] The Action's statement that "it does not appear that the sheets of material are digested with the biological sample" is incorrect. Applicants incorporate the statements made in section (D)(2) above into this section and the following sections by reference.

Neither the cell culture plate in Perlman alone, or in combination with the corresponding membrane, however, appear to be "suitable for at least partial digestion together with said biological sample for subsequent analysis." The teachings of Perlman confirm this:

> The term "a waterproof adhesive sealing membrane" refers to a thin sheet material, i.e., a manufactured film, which blocks any measurable permeation by liquid water and aqueous solutions, and which is coated on its lower surface with a pressure-sensitive adhesive. ***Furthermore, neither the film nor the adhesive can dissolve in water, nor leach any measurable quantity of substances harmful to the growth of cultured eukaryotic and prokaryotic cells during exposure to aqueous solutions, nutrient growth medium, and the like.***

Id. at col. 3, lines 49-58 (emphasis added). This passage confirms that the membrane in Perlman is not configured to be digested with the cells. Such digestion could be harmful to the growth of the cells.

It is also improper for the Action to dismiss the claimed element "storage structure being suitable for at least partial digestion together with said biological sample" as a functional limitation.[2] This element imports a structural limitation to claim 33—that the storage device be at least partially digestible together with a biological sample for subsequent analysis and that the device be configured to store a biological sample. *See, e.g., In re Venezia*, 530 F.2d 956 (CCPA 1976). Perlman does not disclose a device "suitable for at least partial digestion together with" a biological sample. It appears to teach away from such a device. *See* Perlman, col. 3, lines 49-58.

Because Perlman does not teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-47 should therefore be withdrawn.

[2] This applies for all of the anticipation rejections made by the Action.

2. Claims 33-39 and 41-47 Are Not Anticipated By U.S. Patent No. 3,733,025 to Hiersteiner

The Action rejects claims 33-39 and 41-47 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,733,025 to Hiersteiner. The Action contends that this reference discloses an easy opening envelope which has a tamper-evident storage means for storing a sample. The Action also states that the envelope has a backing sheet which is releasably secured to the surface of the cover sheet facing the base sheet.

Applicants traverse. Hiersteiner does not anticipate claims 33-39 and 41-47, either expressly or inherently.

Hiersteiner does not appear to teach or suggest a storage device comprising a "storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis." Hiersteiner does not suggest or even mention that the disclosed envelope is configured to store a biological sample, much less teach that the disclosed envelope is "suitable for at least partial digestion together with" a biological sample for subsequent analysis, as claim 33 requires. This reference also does not appear to suggest a storage structure comprising "a cover sheet configured to be secured to said base sheet, wherein said cover sheet comprises a polymeric film." Claim 55.

Because Hiersteiner does not teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-39 and 41-47 should therefore be withdrawn.

3. Claims 33-35, 41, and 43-47 Are Not Anticipated By U.S. Patent No. 3,965,888 to Bender

The Action rejects claims 33-35, 41, and 43-47 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,965,888 to Bender. The Action contends that this reference discloses a specimen collector and holder. It further contends that the holder includes a

transparent foldable segment that is used to collect the specimen and retain the back-folded segment for visual examination.

Applicants traverse. Bender does not anticipate claims 33-35, 41, and 43-47, either expressly or inherently.

Bender does not appear to teach or suggest a storage device comprising a "storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis." Rather, this reference appears to be directed towards "[a] specimen holder ... for collecting and examining a specimen collected from a body." Bender, Abstract. The holder includes a "transparent adhesive coated foldable segment" that is used to collect the specimen and retain the back-folded segment against a flat transparent portion of the holder. *Id.* "Visual examination of the specimen can then be carried out directly through the transparent holder without transfer of the specimen to glass slides or the like." *Id.*

The specimen holder does not appear to be digestable, much less "suitable for at least partial digestion together with" a biological sample for subsequent analysis. This is confirmed by Bender which states:

> A specimen holder is described for collecting and examining a specimen collected from a body. The holder includes a transparent adhesive coated foldable segment. The adhesive is used to collect the specimen and retain the back-folded segment against a flat transparent portion of the holder. ***Visual examination of the specimen can then be carried out directly through the transparent holder*** without transfer of the specimen to glass slides or the like.

Bender, Abstract (emphasis added). This statement indicates that the specimen holder is configured for examining the specimen and is not "suitable for at least partial digestion" for subsequent analysis.

Because Bender does not teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-35, 41, and 43-47 should therefore be withdrawn.

4. Claims 33-35, 37-39, and 43-47 Are Not Anticipated By U.S. Patent No. 6,007,104 to Draper

The Action rejects claims 33-35, 37-39, and 43-47 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,007,104 to Bender. The Action contends that this reference discloses a multilayer medical device and form for collecting samples and retaining information. The Action states that the left side of the device can take samples and the right side includes information from an individual. According to the Action, the device contains a base sheet and a cover sheet with an adhesive.

Applicants traverse. Draper does not anticipate claims 33-35, 37-39, and 43-47, either expressly or inherently.

Draper does not appear to teach or suggest a storage device comprising a "storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis." Rather, this reference appears to be directed towards "[a] combined medical device and form (20) having a unitary substrate (22) which is divided into a medical device portion (24) and a form portion (26). The form portion (24) of the substrate includes an informational section (30, 32, 34), and form identification material (36)." Draper, Abstract.

The combined medical device does not appear to be digestable, much less "suitable for at least partial digestion together with" a biological sample for subsequent analysis. This is confirmed by Draper which states:

> Because the back cover sheet 74 is attached to the form side of the perforation line 28, the DBS packet is removed from the form portion 24 without the back cover sheet thereby simplifying laboratory processing.

Draper, col. 5, lines 20-23. This statement indicates that the combined medical device is taken apart prior to subsequent examination and is not "suitable for at least partial digestion" for subsequent analysis.

Because Draper does not teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-35, 37-39, and 43-47 should therefore be withdrawn.

G. Conclusion

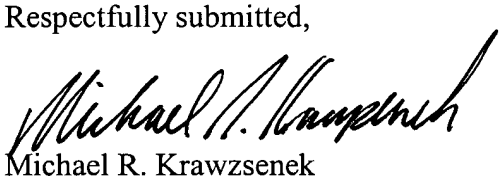
Applicants believe that the present document is a full and complete response to the Office Action dated December 16, 2003. Applicants submit that the present case is in condition for allowance and such favorable action is requested.

A Petition for a Three Month Extension of Time:

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of three months to and including June 9, 2004 in which to respond to the Office Action dated December 16, 2003. Pursuant to 37 C.F.R. § 1.17, a check in the amount of $475.00 is enclosed, which is the process fee for a three-month extension of time for a small entity status. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included, the Commissioner is authorized to deduct or credit the appropriate fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/GENS:008US.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3020 with any questions, comments or suggestions relating to this patent application.

Respectfully submitted,



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